REMARKS/ARGUMENTS

As filed, the application contained claims 1-11. Claims 1-7 and 9 were cancelled in a previous paper. Claim 10 has been amended herein to incorporate the subject matter of claim 11, and claim 11 has been cancelled. In the specification, the first paragraph on page 27, spanning lines 1-8 is now amended to correct an apparent typographical error noted by the Office. No new matter has been added by way of these amendments.

Objection to the Specification

The Office has objected to the paragraph on page 27, lines 1-8, wherein the word "interacted" was apparently misspelled as "interaction". Applicant has re-worded the relevant text substantially as suggested by the Examiner. No new matter has been added by way of this amendment.

Claim Objections

Claim 10 has been objected to because the Office believes there is a typographical error resulting in the word "gencrated" instead of "generated". However, our review of the original MS WORD document and the "as filed e-copies" as well as the electronic copy of the originally filed specification available through the USPTO PAIR system indicated that the word "generated" was spelled properly in the as-filed application and that the putative misspelling "gencrated" is an artifact of the transmission and/or scanning of a document where "e" appears as "c". In particular, our review of the documents filed with the Office indicates that the apparent misspelling of the word "generated" is an artifact of the facsimile transmission and/or Office's scanning of the November 22, 2005

response to the August 23, 2005 Office action. Attached for the examiner's review, as Exhibit 1, is a copy of the claims as originally filed and downloaded from private PAIR showing that the word "generated" is correctly spelled in claim 10. Attached hereto, as Exhibit 2, is a page from the Listing of Claims contained in the October 4, 2004 reply to the office action of September 9, 2004, downloaded from private PAIR, showing that the word "generated" is correctly spelled. Attached hereto, as Exhibit 3, is a page from the Listing of Claims contained in the December 20, 2004 reply to the Office Action of December 3, 2004, downloaded from private PAIR, showing that the word "generated" is spelled correctly. Attached hereto, as Exhibit 4, is a page from the Listing of Claims contained in the June 7, 2005 reply to the Office Action of March 11, 2005, downloaded from private PAIR, showing that the word "generated" is correctly spelled. Attached hereto, as Exhibit 5, is a page from the Listing of Claims contained in the November 22, 2005 reply to the Office Action of August 23, 2005, downloaded from private PAIR showing the apparent spelling of the word "gencrated" results from the facsimile transmission/scanning of the November 22, 2005 reply to the Office Action that is a degradation in the reproduction quality of the 'e' in the word "generated". In short, the word "generated" is spelled correctly throughout applicants' correspondence with the Office including the original as-filed specification and claim set. Applicants respectfully request that the objection be withdrawn.

Rejections of Claims 8 and 10-11 Under 35 U.S.C. § 112, First Paragraph, related to Enablement and Deposit Requirements

In the Office Action, claims 8 and 10-11 were rejected under 35 U.S.C. §112, first paragraph, as failing to enable the full scope of the claims. In particular, the Office states that, though a deposit of the sequence listing has been made with the NCBI, this deposit must be made in accordance with the Budapest Treaty. However, Applicants believe the requirement for deposit under the Budapest Treaty is unnecessary for the following reasons.

Relevant to the present discussion is 37 CFR § 1.801, which states: "the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material."

However, not all biological materials need not be deposited in accordance with the Budapest Treaty. In this regard, 37 C.F.R. § 1.802 states: "Biological material need not be deposited, inter alia, *if it can be made or isolated without undue experimentation.*" In addition, MPEP § 2404.02 states: "No deposit is required, however, *where the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test.*" In the present case, the biological material at issue, and explicitly recited in claims 8 and 10, is the AeSCP-2 polypeptide having the sequence set forth in SEQ ID NO: 3.

Applicant firmly believes the recited polypeptide sequence of SEQ ID NO:3 is biological material within the exception noted in 37 C.F.R. § 1.802 and MPEP § 2404.02. The present application contains examples describing the isolation and characterization of the entire coding sequence of the AeSCP-2 gene (SEQ ID NO:1), the complete cDNA of the AeSCP-2 gene (SEQ ID NO: 2), and determination of the amino acid sequence of the translated polypeptide (SEQ ID NO: 3). Applicant notes that the deposit at issue here was a deposit of *sequence information to a sequence database*, this deposit did *not* entail the physical deposit of a biological material. The NCBI EST databank accepts for submission nucleotide and amino acid sequences accessible to any party including the Commissioner, has no restrictions on availability, and is maintained by the National Institutes of Health with no anticipated closing of the databank in the foreseeable future. In comparison, the American Type Culture Collection (ATCC), a U.S.-based Budapest Treaty Depository, does not accept polynucleotide or amino acid sequence information and allows certain restrictions on material availability. (see copy of current ATCC webpage attached hereto as Exhibit 6).

Upon reviewing the as-filed application, an artisan would certainly require no more than routine experimentation to obtain the recited AeSCP-2 polypeptide. For example, the artisan may proceed by screening an *Aedes aegypti* cDNA library with a nucleic acid probe derived from SEQ ID NO:1 (the coding sequence of AeSCP-2, as disclosed in the present application) to obtain a nucleic acid encoding the AeSCP-2 polypeptide. The preparation of a suitable AeSCP-2 cDNA library is described in, e.g., Krebs, et al. (2002) Use of Subtracted Libraries and Macroarray to isolate Developmentally Specific Genes from the Mosquito, *Aedes aegypti*. Insect Biohem. Mol.

Biol. 32(12): 1757-67, published before the priority date of this application. Accordingly, the screening and isolation procedures to obtain nucleic acids encoding AeSCP-2 polypeptides require no more than routine experimentation.

Subsequent expression of the respective polypeptide would also be routine, and, in fact, guidance for such protein expression is provided in the present application at pages 39-40 where the production of recombinant AeSCP-2 (rAeSCP-2) is described. Reliable screening tests allowing the artisan to confirm possession of an AeSCP-2 polypeptide are made possible by the present disclosure of both AeSCP-2 nucleic acid and polypeptide sequences (SEQ ID NOs: 1-3). For example, the artisan may sequence a nucleic acid or polypeptide and compare that sequence to SEQ ID NO:1 or 2, respectively. In addition, the present application provides guidance in producing AeSCP-2-specific polyclonal antibodies, which are useful in the further identification of AeSCP-2 polypeptides.

In an alternative approach, the polypeptide described by SEQ ID NO: 3 can be chemically-synthesized based on no further information than that disclosed in the present application. Any number of vendors, both educational institutions and commercial ventures, offer polypeptide synthesis services. Examples of such vendors include, for example, the University of Wisconsin Biotechnology Center (see for example http://www.biotech.wisc.edu/ServicesResearch /Peptide/PeptideSynth/), the Medical College of Wisconsin Protein/DNA Facility (see for example http://www.biochem.mcw.edu/protein_facility/price_list.html) and Celtek Custom Peptide Synthesis (http://www.celtek-peptides.com/), to name a few.

Finally, the Federal Circuit has visited a similar issue with respect to the experimentation necessary to practice a disclosed procedure in Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338. In *Ajinomoto* the Federal Circuit affirms the lower court ruling quoting the district court:

> According to the record, all of the methods needed to practice the invention were well known to those skilled in the art. Despite the diversity existing among bacteria, practitioners of this art were prepared to carry out the identification, isolation, recombination, and transformation steps required to practice the full scope of the claims.

Id. at 1345. The Court continued, "the claimed process used conventional and well-known genetic engineering techniques." Id. In Ajinmoto, biological material, a particular yeast strain, was at issue. Obtaining the recited strain required various screening and isolation procedures. However, the court found that it was within the skill of those in the art to screen and obtain the recited cell type based on the disclosure and general methodology; a deposit of the recited yeast strain under the Budapest Treaty was unnecessary to enable the disclosure. The present case appears to be even less unsure in terms of enablement, as both relevant nucleic acid and polypeptide sequences are explicitly disclosed in the application, the source of those materials is publicly available, and general molecular biology procedures (i.e., screening cDNA libaries, protein expression) used to isolate the AeSCP-2 nucleic acids and polypeptides are known in the art.

In summary, the biological material at issue here is the AeSCP-2 polypeptide sequence set forth in SEQ ID NO:3, as presently recited in each of claims 8 and 10. A physical deposit of this material under the Budapest Treaty is not required because the record indicates this biological material can be obtained from publicly available material

with only routine experimentation and, as well, reliable screening tests are known to the artisan for identification of AeSCP-2 polypeptides and related materials. Applicant respectfully requests reconsideration of the rejection under § 112, first paragraph, and withdrawal of the rejection.

Rejection of Claim 10 under 35 U.S.C. § 112, First Paragraph, related to Written Description

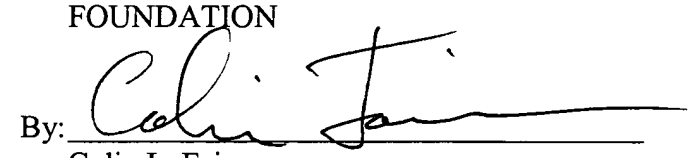
Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification, and the artisan would not be able to reasonably conclude that Applicant had possession of the claimed invention at the time the present application was filed. Specifically, the Office states that the polypeptide recited in the claim is described solely by function, not a structure. In order to move prosecution of this application toward allowance, claim 10 is herein amended to incorporate the subject matter of dependent claim 11, namely, the amino acid sequence of SEQ ID NO:3. This amendment is substantially as suggested by the Examiner and support for the amendment is found, e.g., in the originally-filed claims. Thus, claim 10 now recites a polypeptide having an explicitly-defined structure. Accordingly, the rejection under § 112, first paragraph, is overcome and should now be withdrawn.

CONCLUSION

In light of the amendments and arguments presented herein, Applicant respectfully requests reconsideration and a timely Notice of Allowance to follow in this case. Applicant asks the Examiner to telephone the undersigned in the event a telephone discussion would be helpful in advancing the prosecution of the present case. The Commissioner is authorized to charge any additional fees or underpayment of fees regarding this response, including extensions for reply, to Deposit Account 07-1509.

Respectfully submitted,

WISCONSIN ALUMNI RESEARCH FOUNDATION

Dated: May 15, 2006 By: 

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